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Diabetic Foot Ulcers in a Kenyan Referral and Teaching Hospital: Risk Factors, Patient Characteristics and Clinical Outcomes

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Abstract

Introduction: *The burden of diabetes mellitus (DM) is increasing in resource-poor settings leading to a rise in diabetic complications. Foot complications result in almost half of all hospital admissions among diabetic patients and may result in amputations or death.*

Objective: *To investigate the sociodemographic, clinic-laboratory characteristics and clinical outcomes of patients with diabetic foot ulcers (DFU) in a clinical setting.*

Materials and Methods: *A cross-sectional study of 84 adult consecutive inpatients and outpatients at Kenyatta National Hospital (KNH) with any type of DM and having active DFU was conducted over 12 months. History and physical examinations findings were recorded through a structured questionnaire. Relevant data on the most recent blood tests and clinical outcomes for patients with foot ulcers were retrieved from the patients' medical notes and analysed.*

Results: *Majority (68%) were inpatients. The mean age was 60.30 years with 68% living in urban areas and 60% having minimal or no formal education. 8% were newly diagnosed with DM. The median duration of DM was 6.5 years. A majority (96%) had type 2 diabetes mellitus (T2DM). 45% were on insulin only, 18% on oral drugs only and 32% on a combination of both. The median random blood sugar was 9.60 mmol/L and glycated haemoglobin was 8.80%. Although 61% of patients had co-morbid hypertension, only about 40% had elevated systolic blood pressure (BP) while 23% had elevated diastolic pressures. A majority of the patients had good lipid profile, 85% with desirable total cholesterol and 70% having ideal low-density lipoproteins. The mortality rate among patients with DFU was 11%.*

Conclusion: *There are poor outcomes for patients with DFU in this setting such as poor wound healing, high recurrence rates, increased amputations and mortality compared to previous studies. However, the prevalence of uncontrolled hypertension, dyslipidaemia and neuropathy was much lower than earlier local reports.*

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Keywords: diabetic foot ulcers, Kenya, risk factors, clinical outcomes

Abbreviations: BP: blood pressure; DFU: diabetic foot ulcers; DM: diabetes mellitus; IQR: interquartile range; KNH: Kenyatta National Hospital; T2DM: type 2 diabetes mellitus; UoN: University of Nairobi

Introduction

The global prevalence of DM is 8.8% [1]. By 2030, diabetes will have affected 188 million adults in their fourth and fifth decades and 80% of these patients will come from resource-poor countries [2]. Globally, foot complications result in 25–50% of all hospital admissions in DM patients [3].

In Africa, the prevalence of DFU ranges from 3.2–19.1% [4–10]. A DFU is any foot with ulceration and linked to neuropathy and/or peripheral vascular disease in a patient with DM [11]. Previous reports reveal that the prevalence of diabetic polyneuropathy in Uganda, Kenya and Tanzania vary from 29.4–44% [6, 7, 12, 13]. In addition, 40% of diabetic patients in Nigeria present with the peripheral arterial disease [7]. The occurrence of diabetic amputations, a common complication of DM, varies in Sub-Saharan Africa but is generally thought to be low especially in the rural areas [14, 15]. However, from recent accounts, the prevalence of lower limb amputations among DM patients ranges widely from 11.2–78% [4, 5, 16–19].

Global healthcare expenditure to treat and prevent DM was between USD 376 billion (2010) and 673 billion (2015) [1, 2]. The estimated cost of treating a DFU in resource-rich countries is 6 to 10 times that in resource-poor countries revealing inequalities in access to health resources [20–22]. Moreover, DFU have mortality rates ranging from 2–14.3% in the African setting [4, 23–25).

There is limited data on DFU in Kenya. Previous local publications have looked at the prevalence, associated risk factors, types, and duration of DFU among the study participants [26–29]. There is no mention of outcomes on patients with DFU in the country. The present study aimed to investigate the sociodemographic, clinical characteristics and clinical outcomes of DFU among adult diabetic patients at KNH.

Materials and Methods

These study methods were adapted from studies by Nyamu et al. and Chalya et al. [5, 27].

Study design

A hospital-based cross-sectional study was conducted over 12 months from September 2017 to August 2018. Adult diabetic patients with active DFU were recruited by consecutive sampling from medical inpatient departments and the diabetes outpatient clinic at KNH, Nairobi, Kenya, this is the largest hospital in East and Central Africa.

Data collection

Basic patient and clinical characteristics were collected as part of the routine history taking and usual physical examinations. Patients' basic characteristics included age, sex, area of residence, and level of education. Clinical characteristics including presence of comorbidities, smoking history, alcohol use, duration of diabetes, type of diabetes, duration of DFU, current diabetes medications, previous history of healed foot ulcers, type of DFU, Wagner's classification, and location of the lesion were recorded for each patient. Peripheral neuropathy and peripheral vascular disease were also assessed. Height, weight and BP with the adult cuff standard technique were also measured.

The outcomes of the DFU were collected for patients at the end of the study by reviewing their medical records. Relevant information from the latest case notes, diabetic clinic or medical wards was extracted, classified [complete healing, non-healing, surgical intervention (minor or amputation) or mortality] and analysed.

Statistical analyses

Microsoft® Excel was used for data entry. Descriptive analyses was performed for all variables and data presented in charts and tables. Continuous variables such as age, time and, blood tests were converted into categorical variables using cut-off points. Independent two-tailed t-test was used to compare means, Chi-square test was used to verify the association of categorical variables and one-way ANOVA for comparison across multiple groups. Results were considered significant at $p < 0.05$. All analyses were performed using IBM® SPSS® Statistical Package Version 23.0.

Ethical considerations

Approval was sought from the KNH-UoN Ethics and Research Committee (Approval Number P769/10/2016; website: http://erc.uonbi.ac.ke/) to conduct the study and patients enrolled only after informed consent was taken. Patient confidentiality and data security was guaranteed.

Results

Eighty-four patients were enrolled in the study (Figure 1). Most of the study patients were inpatients (68.4%). The mean age was 60.30 + 12.88 years. The youngest patient was 25 years while the oldest was 108 years, with most patients being in their fifth and sixth decades. The females were 54.1%. Most of the patients (68.3%) lived in urban areas while 31.7% lived in rural areas. A majority of 44.2% had primary education and 15.6% did not have any formal education. Males were more educated than females ($p = 0.001$) (Table 1).

The median interquartile range (IQR) duration of DM was 6.5 (1.25, 12.5). A small proportion, (8.5%) of patients were newly-diagnosed with diabetes, 17.3% had ever smoked cigarettes while 33.3% had ever taken alcohol. Males were more likely to be smokers ($p = 0.004$). Fourteen patients (16.5%) had no comorbidities, while the rest of the patients (83.5%) had one or more comorbidities. The most common comorbidities were hypertension, kidney disease, heart disease and anemia. Most of the study patients had T2DM and were currently on medication (Table 2).

The mean BP was within normal ranges but 39.7% had elevated systolic BP and 23.3% had high diastolic BP. A large number of patients did not have recent laboratory results; 63.53% lacked HbA1c levels, 70% lacked lipid profile tests, 47% lacked liver function tests and 30% lacked kidney function tests. 39.3% of patients had high urea levels and 58.9% had elevated creatinine levels. Females had significantly better creatinine levels. A majority of the patients had desirable lipid profile tests (Table 3).

The median IQR duration of the DFU was 8 (4, 16) weeks. The longest duration of DFU was 312 weeks. Half of the patients had a previous history of DFU and a third had a prior history of amputation. At the time of the study, 77.6% had recently used antibiotics to treat the ulcer. A majority (88.10%) of the patients had ulcers on only one foot. Forty-nine ulcers (53.26%) were located on the right foot and 43 ulcers (46.74%) on the left. Most ulcers were located on the forefoot and hindfoot. The DFU were mainly neuropathic or ischaemic and Wagner Stage 1 or 2. Of all the DFU, 54.3% had signs of diabetic neuropathy (Table 4).

The interval between the first and second interview was calculated and its median IQR was 98 (147) days. A majority of the patients were reviewed within 1–3 months after the first interview (28.9%), 3–6 months (28.9%) and 6–12 months (21.1%). We reviewed 36 patients (42.9%) while 48 patients (57.1%) were lost to follow-up. A majority of the patients had good progress while 25% of the patients on follow-up had non-healing DFU. There was a mortality rate of 11.1% (Figure 2).

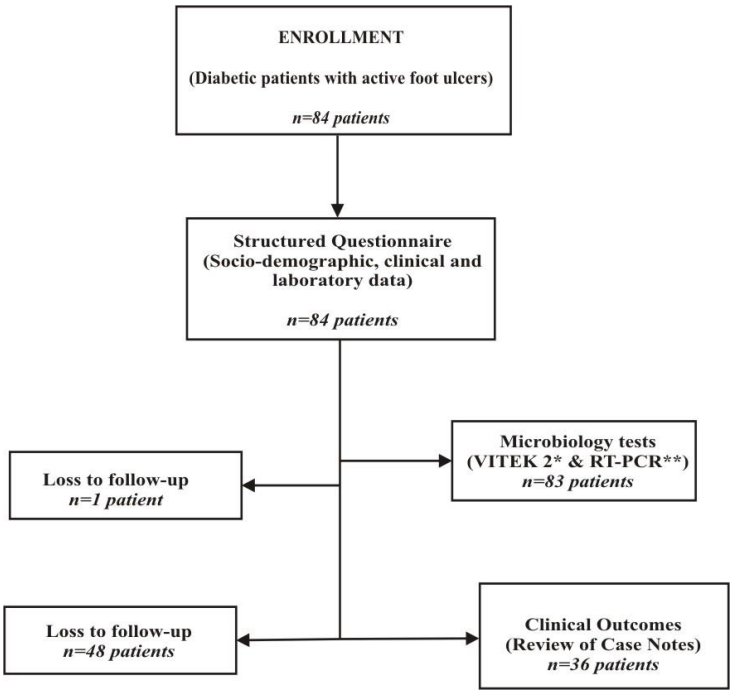

Figure 1: Flow chart of the study. The figure depicts the recruitment of patients into the study and study directed activities. Microbiological procedures and results are described in an earlier publication. *VITEK 2 machine was utilised for automated culture and sensitivity tests; **RT-PCR: real-time polymerase chain reaction.

				n (%)	
Sex		Male		39 (45.9)	
		Female		46 (54.1)	
Age group		≤30		1 (1.2)	
		31–50		15 (18.1)	
		51–65		42 (50.6)	
		66–80		20 (24.1)	
		≥81		5 (6.0)	
		Total population	**Male**	**Female**	**p value**
Age (years) mean (SD)		60.30 (12.88)	58.62 (11.38)	61.65 (13.95)	0.29
Education level n (%)	None	12 (15.6)	2 (5.9)	10 (23.3)	**0.001**
	Primary	34 (44.2)	12 (35.3)	22(51.2)	
	Secondary	24 (31.2)	13 (38.2)	11(25.6)	
	Tertiary	7 (9.1)	7 (20.6)	0 (0.0)	
Residence n (%)	Urban	56 (68.3)	29 (78.4)	27 (60.0)	0.097
	Rural	26(31.7)	8 (21.6)	18 (40.0)	

Table 1: Patients' sociodemographic characteristics. This table shows the sociodemographic characteristics of the study patients. The lower part of the table shows differences in variables across gender and were considered statistically significant at $p < 0.05$.

				n (%)	
Type of diabetes mellitus n (%)		Type 1 DM		2 (2.4)	
		Type 2 DM		81 (96.4)	
		Gestational DM		1 (1.2)	
History of diabetes mellitus n (%)		Yes (previously diagnosed)		75 (91.5)	
		No (newly diagnosed)		7 (8.5)	
Duration of DM (years) median (IQR)		**6.5 (11.25*)**			
Duration of DM (years) n (%)		< 5		36 (46.2)	
		6–10		18 (23.1)	
		10–20		19 (24.4)	
		> 21		5 (6.4)	
Type of treatment n (%)		None		2 (2.4)	
		Diet		1 (1.2)	
		OHA		15 (17.6)	
		Insulin		38 (44.7)	
		Both diet and OHA		2 (2.4)	
		Both OHA and insulin		27 (31.8)	
Risk factors		**Total population**	**Male**	**Female**	**p value**
Smoking habits n (%)	Yes	13 (17.3)	11 (31.4)	2 (5.0)	**0.004**
	No	62 (82.7)	24 (68.6)	38 (95.0)	
Alcohol intake n (%)	Yes	25 (33.3)	18 (51.4)	7 (17.5)	**0.003**
	No	50 (66.7)	17 (48.6)	33 (82.5)	
Number of comorbidities n (%)	None	14 (16.5)	7 (17.9)	7 (15.2)	0.509
	1	33 (38.8)	15 (38.5)	18 (39.1)	
	2	19 (22.4)	7 (17.9)	12 (26.1)	
	3	13 (15.3)	5 (12.8)	8 (17.4)	
	4	5 (5.9)	4 (10.3)	1 (2.2)	
	5	1 (1.2)	1 (2.6)	0 (0.0)	

Table 2: Clinical characteristics from patients' history. This table represents descriptive statistics of the clinical findings from patients' medical history, where both mean and median were reported, the data was not normally distributed. Differences across gender were statistically significant when $p < 0.05$.

Parameter	Total mean (SD)	Total median (IQR)	Male	Female	p value
Systolic blood pressure (mmHg)	136.05 (34.51)		138.25 (34.72)	138.39 (24.77)	0.985
Diastolic blood pressure (mmHg)	80.08 (18.74)		80.56 (19.47)	80.61 (12.41)	0.991
RBS[1] (mmol/L)	14.12 (11.03)	9.60 (8.95)	10.08 (4.96)	11.57 (7.28)	0.373
HbA1c[2] (%)	8.40 (2.29)	8.80 (2.80)	9.59 (3.75)	8.51(1.74)	0.358
Urea (mmol/L)	12.05 (10.58)	7.1 (11.85)	19.36 (20.90)	9.67 (16.68)	**0.049**
Creat[3] (mmol/L)	147.53 (74.06)	114.55 (111.2)	228.19 (156.38)	133.12 (100.72)	**0.015**
LDL-C[4] (mmol/L)	1.40 (0.34)	1.51 (0.81)	1.65 (0.90)	1.82 (0.79)	0.627
Albumin (g/L)	29.97 (6.81)		28.5 (7.53)	30.66 (6.46)	0.333

Table 3: Clinical and laboratory parameters. This table represents descriptive statistics of the clinical and laboratory parameters from physical examination and reviewing of patients' clinical records, where both mean and median were reported, the data was not normally distributed. Statistically significant $p < 0.05$. [1]Random blood sugar [2]Glycated hemoglobin [3]Creatinine [4]Low-density lipoprotein-cholesterol.

			n (%)	
Duration of DFU (weeks) 8 (12*)				
Duration of DFU (weeks) n (%)		> 6	27 (37.5)	
		7–26	38 (52.8)	
		27–52	7 (9.7)	
		> 52	0 (0.0)	
History of previous DFU n (%)		Yes	40 (50)	
		No	40 (50)	
History of previous amputation n (%)		Yes	26 (33.3)	
		No	52 (66.7)	
History of any recent antibiotic use n (%)		Yes	45 (77.6)	
		No	13 (22.4)	
		Right	**Left**	**Total**
Anatomic site of foot ulcer n (%)	Forefoot	25 (51.0)	24 (55.8)	49 (53.3)
	Midfoot	7 (14.3)	2 (4.7)	9 (9.8)
	Hindfoot	11 (22.4)	16 (37.2)	27 (29.4)
	Forefoot & midfoot	4 (8.2)	0 (0.0)	4 (4.4)
	Midfoot & hindfoot	1 (2.0)	0 (0.0)	1 (1.1)
	Forefoot, midfoot & hindfoot	1 (2.0)	1 (2.3)	2 (2.2)
Type of ulcer n (%)	Ischaemic	20 (40.8)	22 (51.2)	42 (45.6)
	Neuropathic	25 (51.0)	18 (41.9)	43 (46.7)
	Neuroischaemic	4 (8.2)	3 (7.0)	7 (7.6)
Wagner stage n (%)	0	1 (2.0)	0 (0.0)	1 (1.1)
	1	11 (22.4)	16 (37.2)	27 (29.4)
	2	16 (32.7)	12 (27.9)	28 (30.4)
	3	10 (20.4)	9 (20.9)	19 (20.7)
	4	10 (20.4)	4 (9.3)	14 (15.2)
	5	1 (2.0)	2 (4.7)	3 (3.3)

Table 4: Clinical characteristics of the DFU. This table represents duration, types, location and other clinical characteristics of DFU among the study patients. *The interquartile range of duration of DFU was from 4 to 16.

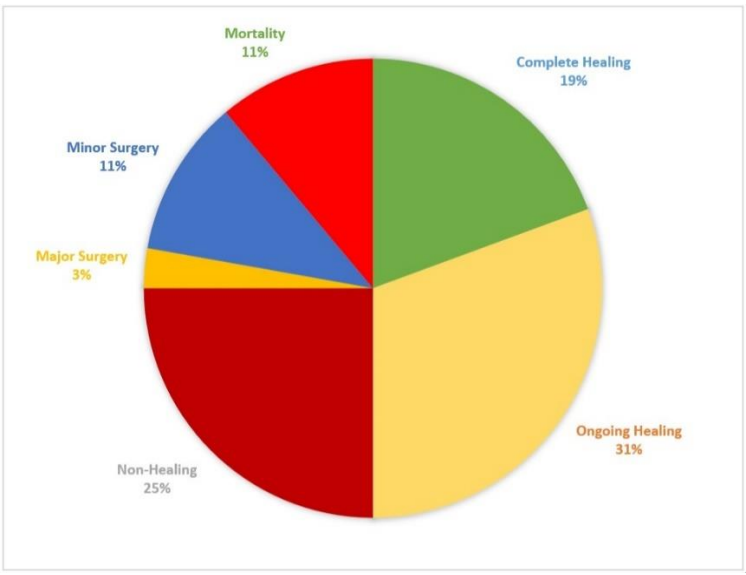

Figure 2: Distribution of clinical outcomes of DFU for the study patients. The chart depicts the proportion of study patients reviewed with a particular outcome of interest. Complete and ongoing healing were considered to be good outcomes while non-healing wounds and mortality as poor outcomes.

Discussion

Africa is the second most common region to be affected by DFU according to a recent global meta-analysis [30]. In the present study, there was a high recurrence rate of DFU (50%), comparable to facilities that follow best practices (70%) [31]. This warrants further investigation to see if patients who have had prior DFU adhere to proper foot care.

The mean age of patients in this study was slightly higher than in earlier studies [5, 27, 29]. Most of the study patients were however in their fifth and sixth decades just like in other studies in East Africa [5, 8, 9, 28, 29]. There were more females than males enrolled in this present study similar to an earlier study in Kenya but in contrast to other studies in Sudan, Tanzania, and Ethiopia where males were more [5, 8, 27, 28, 32].

In the present study, about 60% had minimal or no formal education similar to studies in Sudan and Tanzania [5, 32]. Moreover, a majority of patients in this study were from urban areas similar to publications from Sudan and Ethiopia [9, 10, 32]. A study in Tanzania also enrolled patients mainly from rural areas [5]. In this current study, more patients were from urban areas mainly because of KNH's location in Nairobi.

Mariam et al. reported T2DM to be a significant risk factor for developing a DFU [9]. In this present study, almost all of the patients had T2DM. A small proportion of the study patients were newly-diagnosed with DM comparable to an earlier study [27]. The median duration of DM was 6.5 years, revealing that DFU are developing much earlier than before. This could be an indicator of poor foot care or inadequate foot care.

In the present study, only a small proportion of patients were not on medication. A majority were on insulin therapy, whether alone or in combination with oral drugs. The high number of patients on insulin could result from the fact that inpatients often have deranged glucose levels and require insulin for strict glucose control. However, less than half of the current study patients were on insulin therapy only which is comparable to earlier studies in Kenya and Ethiopia [9, 27]. Although poor glycaemic control often leads to DFU, insulin treatment is in itself a risk factor for developing DFU in Tanzania [6, 27, 29]. The glycemic control based on HbA1c level for patients in this present study was similar to an earlier study in KNH but much worse than in a recent study in rural Kenya [27, 29].

The prevalence of uncontrolled hypertension in this study was much lower than an earlier study in Kenya [29]. In the current study, the rates of kidney disease were similar to findings in Ethiopia, while heart disease was higher than in

Sudan [8, 32]. In this present study, the lipid profile was much better than that reported by Nyamu et al. and could be a result of improved patient awareness or better management of dyslipidaemia by the clinicians [27].

The median duration of DFU was 8 weeks in this current study. This was shorter than in earlier studies in Kenya and Tanzania and could perhaps indicate increased patient awareness, increased foot care, and increased foot care assessment by the clinicians [5, 27]. DFU is often undiagnosed because of both patient or clinician related factors [33]. It is important that patients examine their feet regularly and clinicians not to omit to ask or examine for the diabetic foot.

Neuropathy is a significant risk factor for developing DFU [6, 9]. Peripheral neuropathy usually begins with autonomic dysfunction, then sensory nerves are affected and finally motor nerves deteriorate [31]. Although the prevalence of neuropathy in this present study is much lower than in earlier Kenyan studies [27, 28], diabetic polyneuropathy among the study patients was much higher than in Uganda and Nigeria [7, 12]. This confirms a higher rate of neuropathy among Kenyan patients. A majority of the DFU in this present study was in Wagner Stage 1 and 2 in contrast to studies in Tanzania and Libya [5, 24]. This could also indicate an early presentation of the patients to this hospital.

In the present study, a third of the study patients had a prior amputation, which was thrice the rate of previous amputation in Tanzania [5]. However, after follow-up, only 14% of patients had a surgical procedure compared to 90% in Tanzania, mainly because the current study was conducted in medical and not surgical departments [5]. Half of the patients followed-up in this present study had good clinical outcomes. The mortality rate in this present study was high and similar to the study in Tanzania and a literature review from 19 African countries [4, 5]. Mortality in Tanzania was associated with diabetes complications and advanced DFU [5]. In this present study, there was a non-healing rate of 25% among the study patients who were followed-up. Healing of wounds is a complex immunological response to injury [20, 31, 33].

Limitations

One of the limitations in this study is that funding for this study was allocated towards microbiological tests to isolate the bacteria from DFU as presented in an earlier publication [34]. As such, we relied on extraction of clinical data from patients medical records for retrieval of laboratory tests. Moreover, outcome of DFU in some instances depended on the review of medical notes and not repeat physical examinations.

Conclusion

There are poor outcomes for patients with DFU in this setting such as poor wound healing, high recurrence rates, increased lower-limb amputations and mortality compared to previous studies. The study patients were slightly older, female less educated but urbanised. The study patients had better control of hypertension and dyslipidaemia, lower levels of neuropathy and earlier presentation of DFU reflecting increased patient awareness and better management by clinicians. Majority of the patients in this study were on insulin and antibiotics.

Recommendations

We recommend the following:

- The high prevalence of poor outcomes for patients with DFU warrants the need to investigate bio-psychosocial risk factors.
- Screening and foot assessment should be encouraged during each clinical visit. Examination focuses on peripheral neuropathy, peripheral arterial disease and plantar pressure [31]. Certain professional organisations recommend different prevention measures based on the patients' risk levels [20]. Patients with DM should be educated on smoking cessation and foot-care.
- Patients with DM should have laboratory tests such as UECs, LFTs, Lipid profile, and HbA1c every 6 months to rule out and properly manage diabetic complications.

Conflicts of Interest

The authors declare that they have no competing interests.

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DMM received partial funding from KNH Research and Programs Department (KNH Study Registration Number: Med/101/2017) to conduct this study (website: http://knh.or.ke/). Most of the funding sought was for microbiology tests and PCR tests presented in an earlier publication. The funders had no role in study design, data collection and analysis, decision to publish or preparation of the manuscript.

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